Amendments to the Claims:

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims:

1. (Currently Amended) A method for sterilizing a biological material that is sensitive to ionizing radiation, said method comprising:

(i) reducing the residual solvent content of a biological material to a level effective to protect said biological material from said ionizing radiation; and

(ii) irradiating said biological material with a suitable ionizing radiation at an effective rate for a time effective to sterilize said biological material, wherein ~~at least one sensitizer is added to said biological material prior to step (ii)~~ said effective rate is not constant for the duration of the sterilization procedure.

C2

2. (Original) The method according to claim 1, wherein said solvent is water.

3. (Original) The method according to claim 1, wherein said solvent is an organic solvent.

4. (Currently Amended) The method according to claim 1, wherein said biological material [[is]] contains blood or [[a]] at least one component of blood.

5. (Currently Amended) The method according to claim 1, wherein said biological material [[is a]] contains at least one proteinaceous material.

6. (Currently Amended) The method according to claim 5, wherein said at least one proteinaceous material is [[a]] at least one component of blood.

7. (Currently Amended) The method according to claim 1, wherein said biological material [[is a]] contains at least one clotting factor.

C 2

8. (Currently Amended) The method according to claim 7, wherein said clotting factor is at least one member selected from the group consisting of: Factor II, Factor V, Factor VII, Factor VIIa, Factor VIII, Factor IX, Factor X, Factor XIII, Factor XIIIa, Von Willebrand's Factor, prothrombin and Fibrinogen.

9. (Currently Amended) The method according to claim 1, wherein said biological material [[is]] contains at least one member selected from the group consisting of: albumin, immunoglobulin A, immunoglobulin G, immunoglobulin M, immunoglobulin E and mixtures of one or more immunoglobulins.

10. (Currently Amended) The method according to claim 1, wherein said biological material [[is]] contains mammalian tissue or [[a]] at least one component of mammalian tissue.

11. (Currently Amended) The method according to claim 1, wherein said biological material [[is a]] contains at least one recombinantly-produced biological material.

12. (Currently Amended) The method according to claim 1, wherein said biological material [[is a]] contains at least one transgenic biological material.

C 2

13. (Currently Amended) The method according to claim 1, wherein said biological material [[is a]] contains a member selected from the group consisting of food products, [[or a]] botanical products and combinations thereof.

14. (Original) The method according to claim 1, wherein said ionizing radiation is gamma radiation.

15. (Currently Amended) The method according to claim 1, wherein said biological material [[is a]] contains a member selected from the group consisting of carbohydrates, [[or]] polysaccharides and combinations thereof.

16. (Currently Amended) The method according to claim 1, wherein said biological material [[is]] contains at least one member selected from the group consisting of chitin, chitosan, NOCC-chitosan and derivatives thereof.

17. (Currently Amended) The method according to claim 1, wherein said biological material [[is a]] contains at least one product of cellular metabolism.

18. (Currently Amended) The method according to claim 1, wherein said effective rate [[is]] comprises a rate of not more than [[about]] 3.0 kGy/hr.

C 2

19. (Currently Amended) The method according to claim 1, wherein said effective rate [[is]] comprises a rate of more than [[about]] 3.0 kGy/hr.

20. (Currently Amended) The method according to claim 1, wherein said effective rate [[is]] comprises a rate of not more than [[about]] 6.0 kGy/hr.

21. (Currently Amended) The method according to claim 1, wherein said effective rate [[is]] comprises a rate of not more than [[about]] 18.0 kGy/hour.

22. (Currently Amended) The method according to claim 1, wherein said effective rate [[is]] comprises a rate of not more than [[about]] 30.0 kGy/hour.

23. (Original) The method according to claim 1, wherein said biological material is maintained in a low oxygen atmosphere.

24. (Original) The method according to claim 23, wherein said biological material is maintained in an argon atmosphere.

25. (Currently Amended) The method according to claim 1 ~~any one of claims 1-24~~, wherein said residual solvent content is reduced by lyophilization.

C 2

26. (Currently Amended) The method according to claim 25, wherein said residual solvent content is less than [[about]] 2.0%.

27. (Currently Amended) The method according to claim 25, wherein said residual solvent content is less than [[about]] 1.0%.

28. (Currently Amended) The method according to claim 25, wherein said residual solvent content is less than [[about]] 0.5%.

29. (Cancelled).

30. (Currently Amended) A method for sterilizing a biological material that is sensitive to ionizing radiation, said method comprising:

(i) adding to a biological material at least one stabilizer in an amount effective to protect said biological material from said ionizing radiation~~, wherein said at least one stabilizer is selected from the group consisting of: ascorbic acid or a salt or ester thereof, DMSO, trehalose, mannitol, glutathione, tocopherol, 6-hydroxy-2,5,7,8-tetramethylchroman-2-carboxylic acid, polyhydric alcohols, rutin and other flavanoids~~; and

(ii) irradiating said biological material with a suitable ionizing radiation at an effective rate for a time effective to sterilize said biological material, wherein said effective rate is not constant for the duration of the sterilization procedure.

C2

31-33. (Cancelled)

34. (Currently Amended) A method for sterilizing a biological material that is sensitive to ionizing radiation, said method comprising:

(i) reducing the residual solvent content of a biological material to a level effective to protect said biological material from said ionizing radiation;

(ii) adding to said biological material at least one stabilizer in an amount effective to protect said biological material from said ionizing radiation~~, wherein said at least one stabilizer is selected from the group consisting of: ascorbic acid or a salt or ester thereof,~~

~~DMSO, trehalose, mannitol, glutathione, tocopherol, 6-hydroxy-2,5,7,8-tetramethylchroman-2-carboxylic acid, polyhydric alcohols, rutin and other flavanoids~~; and

(iii) irradiating said biological material with a suitable ionizing radiation at an effective rate for a time effective to sterilize said biological material, wherein said effective rate is not constant for the duration of the sterilization procedure and steps (i) and (ii) may be performed in any order.

35. (Cancelled).

36. (Currently Amended) The method according to claim 30, wherein said biological material [[is]] contains blood or [[a]] at least one component of blood.

37. (Currently Amended) The method according to claim 30, wherein said biological material [[is a]] contains at least one proteinaceous material.

38. (Currently Amended) The method according to claim 37, wherein said at least one proteinaceous material is [[a]] at least one component of blood.

39. (Currently Amended) The method according to claim 30, wherein said biological material [[is a]] contains at least one clotting factor.

40. (Currently Amended) The method according to claim 39, wherein said clotting factor is at least one member selected from the group consisting of: Factor II, Factor V, Factor VII, Factor VIIa, Factor VIII, Factor IX, Factor X, Factor XIII, Factor XIIIa, Von Willebrand's Factor, prothrombin and Fibrinogen.

41. (Currently Amended) The method according to claim 30, wherein said biological material [[is]] contains at least one member selected from the group consisting of: albumin, immunoglobulin A, immunoglobulin G, immunoglobulin M, immunoglobulin E and mixtures of one or more immunoglobulins.

C 2

42. (Currently Amended) The method according to claim 30, wherein said biological material [[is]] contains mammalian tissue or [[a]] at least one component of mammalian tissue.

43. (Currently Amended) The method according to claim 30, wherein said biological material [[is a]] contains at least one recombinantly-produced biological material.

44. (Currently Amended) The method according to claim 30, wherein said biological material [[is a]] contains at least one transgenic biological material.

45. (Currently Amended) The method according to claim 30, wherein said biological material [[is a]] contains a member selected from the group consisting of food products, [[or a]] botanical products and combinations thereof.

46. (Previously Presented) The method according to claim 30, wherein said ionizing radiation is gamma radiation.

47. (Currently Amended) The method according to claim 30, wherein said biological material [[is a]] contains a member selected from the group consisting of carbohydrates, [[or]] polysaccharides and combinations thereof.

C 2

48. (Currently Amended) The method according to claim 30, wherein said biological material [[is]] contains at least one member selected from the group consisting of chitin, chitosan, NOCC-chitosan and derivatives thereof.

49. (Currently Amended) The method according to claim 30, wherein said biological material [[is a]] contains at least one product of cellular metabolism.

50. (Currently Amended) The method according to claim 30, wherein said effective rate [[is]] comprises a rate of not more than [[about]] 3.0 kGy/hr.

51. (Currently Amended) The method according to claim 30, wherein said effective rate [[is]] comprises a rate of more than [[about]] 3.0 kGy/hr.

52. (Currently Amended) The method according to claim 30, wherein said effective rate [[is]] comprises a rate of not more than [[about]] 6.0 kGy/hr.

53. (Currently Amended) The method according to claim 30, wherein said effective rate [[is]] comprises a rate of not more than [[about]] 18.0 kGy/hour.

54. (Currently Amended) The method according to claim 30, wherein said effective rate [[is]] comprises a rate of not more than [[about]] 30.0 kGy/hour.

C2

55. (Previously Presented) The method according to claim 30, wherein said biological material is maintained in a low oxygen atmosphere.

56. (Previously Presented) The method according to claim 55, wherein said biological material is maintained in an argon atmosphere.

57. (Previously Presented) The method according to claim 34, wherein said solvent is water.

58. (Previously Presented) The method according to claim 34, wherein said solvent is an organic solvent.

59. (Currently Amended) The method according to claim 34, wherein said biological material [[is]] contains blood or [[a]] at least one component of blood.

60. (Currently Amended) The method according to claim 34, wherein said biological material [[is a]] contains at least one proteinaceous material.

61. (Currently Amended) The method according to claim 60, wherein said at least one proteinaceous material is [[a]] at least one component of blood.

C 2

62. (Currently Amended) The method according to claim 34, wherein said biological material [[is a]] contains at least one clotting factor.

63. (Currently Amended) The method according to claim 62, wherein said clotting factor is at least one member selected from the group consisting of: Factor II, Factor V, Factor VII, Factor VIIa, Factor VIII, Factor IX, Factor X, Factor XIII, Factor XIIIa, Von Willebrand's Factor, prothrombin and Fibrinogen.

64. (Currently Amended) The method according to claim 34, wherein said biological material [[is]] contains at least one member selected from the group consisting of: albumin, immunoglobulin A, immunoglobulin G, immunoglobulin M, immunoglobulin E and mixtures of one or more immunoglobulins.

65. (Currently Amended) The method according to claim 34, wherein said biological material [[is]] contains mammalian tissue or [[a]] at least one component of mammalian tissue.

66. (Currently Amended) The method according to claim 34, wherein said C 2 biological material [[is a]] contains at least one recombinantly-produced biological material.

67. (Currently Amended) The method according to claim 34, wherein said biological material [[is a]] contains at least one transgenic biological material.

68. (Currently Amended) The method according to claim 34, wherein said biological material [[is a]] contains a member selected from the group consisting of food products, [[or a]] botanical products and combinations thereof.

69. (Previously Presented) The method according to claim 34, wherein said ionizing radiation is gamma radiation.

70. (Currently Amended) The method according to claim 34, wherein said biological material [[is a]] contains a member selected from the group consisting of carbohydrates, [[or]] polysaccharides and combinations thereof.

71. (Currently Amended) The method according to claim 34, wherein said biological material [[is]] contains at least one member selected from the group consisting of chitin, chitosan, NOCC-chitosan and derivatives thereof.

C 2

72. (Currently Amended) The method according to claim 34, wherein said biological material [[is a]] contains at least one product of cellular metabolism.

73. (Currently Amended) The method according to claim 34, wherein said effective rate [[is]] comprises a rate of not more than [[about]] 3.0 kGy/hr.

74. (Currently Amended) The method according to claim 34, wherein said effective rate [[is]] comprises a rate of more than [[about]] 3.0 kGy/hr.

75. (Currently Amended) The method according to claim 34, wherein said effective rate [[is]] comprises a rate of not more than [[about]] 6.0 kGy/hr.

76. (Currently Amended) The method according to claim 34, wherein said effective rate [[is]] comprises a rate of not more than [[about]] 18.0 kGy/hour.

77. (Currently Amended) The method according to claim 34, wherein said effective rate [[is]] comprises a rate of not more than [[about]] 30.0 kGy/hour.

78. (Previously Presented) The method according to claim 34, wherein said biological material is maintained in a low oxygen atmosphere.

C2

79. (Previously Presented) The method according to claim 78, wherein said biological material is maintained in an argon atmosphere.

80. (Currently Amended) The method according to ~~any one of claims~~ claim 34 ~~or 57-79~~, wherein said residual solvent content is reduced by lyophilization.

81. (Currently Amended) The method according to claim 80, wherein said residual solvent content is less than [[about]] 2.0%.

82. (Currently Amended) The method according to claim 80, wherein said residual solvent content is less than [[about]] 1.0%.

83. (Currently Amended) The method according to claim 80, wherein said residual solvent content is less than [[about]] 0.5%.

84-172 (Cancelled).

173. (New) The methods according to claim 1, wherein at least one sensitizer is added to said biological material prior to step (ii).

174. (New) The methods according to claim 30, wherein at least one sensitizer is added to said biological material prior to step (ii).

C 2

175. (New) The methods according to claim 34, wherein at least one sensitizer is added to said biological material prior to step (iii).

176. (New) The method according to claim 30, wherein said at least one stabilizer is an antioxidant.

177. (New) The method according to claim 30, wherein said at least one stabilizer is a free radical scavenger.

178. (New) The method according to claim 30, wherein said at least one stabilizer is at selected from the group consisting of : ascorbic acid or a salt or ester thereof, glutathione, tocopherol, 6-hydroxy-2,5,7,8-tetramethylchroman-2-carboxylic acid, flavanoids and combinations thereof.

179. (New) The method according to claim 34, wherein said at least one stabilizer is an antioxidant.

C 2

180. (New) The method according to claim 34, wherein said at least one stabilizer is a free radical scavenger.

181. (New) The method according to claim 34, wherein said at least one stabilizer is at selected from the group consisting of : ascorbic acid or a salt or ester thereof, glutathione, tocopherol, 6-hydroxy-2,5,7,8-tetramethylchroman-2-carboxylic acid, flavanoids and combinations thereof.

182. (New) The method according to claim 1, wherein said effective rate comprises a rate of about 3.0 kGy/hr.

183. (New) The method according to claim 182, wherein said effective rate further comprises a rate of about 2.0 kGy/hr.

184. (New) The method according to claim 30, wherein said effective rate comprises a rate of about 3.0 kGy/hr.

185. (New) The method according to claim 184, wherein said effective rate further comprises a rate of about 2.0 kGy/hr.

186. (New) The method according to claim 34, wherein said effective rate comprises a rate of about 3.0 kGy/hr.

C2

187. (New) The method according to claim 186, wherein said effective rate further comprises a rate of about 2.0 kGy/hr.

188. (New) The method according to claim 1, wherein said irradiating is carried out below ambient temperature.

189. (New) The method according to claim 30, wherein said irradiating is carried out below ambient temperature.

190. (New) The method according to claim 34, wherein said irradiating is carried out below ambient temperature.

191. (New) The method according to claim 1, wherein said irradiating is carried out below the freezing point of said biological material.

192. (New) The method according to claim 30, wherein said irradiating is carried out below the freezing point of said biological material.

193. (New) The method according to claim 34, wherein said irradiating is carried out below the freezing point of said biological material.

C2 194. (New) The method according to claim 1, wherein said irradiating is carried out below the eutectic point of said biological material.

195. (New) The method according to claim 30, wherein said irradiating is carried out below the eutectic point of said biological material.

196. (New) The method according to claim 34, wherein said irradiating is carried out below the eutectic point of said biological material.